

**Formal Matters**

**Supplemental IDS**

Submitted herewith is a Supplemental Information Disclosure Statement in which Applicants have identified document EP 302,772 that the Examiner may wish to consider in connection with the examination of the above-identified application. Submission of this Supplemental Information Disclosure Statement is not an admission that the identified document is material to the patentability of the above-identified application.

**Art Rejection**

Claims 1-9 and 20-30 have been rejected under 35 U.S.C. 103 as being unpatentably obvious over Gangadharan et al. (U.S. Patent 5,643,582) in view of Szentmiklósi et al. (U.S. Patent 5,244,880) and Davidson et al. (U.S. Patent 6,080,783). The Examiner contends that it would have been obvious to incorporate the pyroglutamic acid disclosed in Szentmiklósi et al. and the zinc salt disclosed in Davidson et al. into a composition of Gangadharan et al., to thereby realize Applicants' invention, notwithstanding Szentmiklósi et al.'s failure to disclose nasal formulations and Davidson et al.'s failure to disclosure nasal compositions comprising pyroglutamic acid. Applicants respectfully traverse this rejection.

Gangadharan et al. disclose moisturizers which are suitable for rehydrating or maintaining hydration in skin and mucous membranes, and which comprise bioadhesives in combination with humectants and water complexing agents. Suitable humectants disclosed in the Gangadharan et al. reference include 2-pyrrolidinone-5-carboxylic acid salts (i.e., pyroglutamic acid salts). Gangadharan et al. further disclose that the moisturizers can also comprise other compositional ingredients that include preservatives such as benzoic acid and its salts wherein the benzoic acid compounds can also be used as acidulants, and that include pH adjusting acidulant materials to adjust the pH value of the composition between 3-5 for vaginal applications. Furthermore, Gangadharan et al. disclose that the moisturizers can be administered to different epithelial cells for dermis and mucous membrane contact including the epithelial cells of the buccal and nasal regions. Gangadharan et al., however, fail to disclose a moisturizer in the form of a nasal composition that comprises a combination of a pyroglutamic acid and an organic acid having a dissociation constant (pKa) value of from about 3.0 to about 5.0.

Szentmiklósi et al. disclose pharmaceutical and cosmetic compositions which comprise aqueous solutions of primycin and pyroglutamic acid. In addition to primycin and pyroglutamic acid, Szentmiklósi et al. disclose that the pharmaceutical or cosmetic compositions can optionally comprise other therapeutic actives such as antibacterial (e.g., oxolinic acid) and/or anti-inflammatory agents. The compositions disclosed in the Szentmiklósi et al. reference are further described as clear, stable aqueous solutions which are formulated as topically applicable pharmaceutical compositions and disinfecting cosmetic compositions. Szentmiklósi et al., however, fail to disclose a pharmaceutical composition in the form of a nasal composition, and certainly fail to disclose a nasal composition comprising pyroglutamic acid in combination with an organic acid having a dissociation constant (pKa) value of from about 3.0 to about 5.0.

Davidson et al. disclose a viscous gel which is suitable for delivering zinc or another metal to the nasal membrane. The viscous gel of Davidson et al. comprises a carrier and preferably a zinc gluconate compound wherein the zinc gluconate produces concentrations of ionic zinc for delivery into the nasal cavity. Davidson et al. further disclose that the viscous gel has a viscosity in the range of from 5,000 to 20,00 centipoise to facilitate maintenance of the gel in the nasal cavity. Davidson et al., however, fail to disclose a nasal composition comprising a combination of pyroglutamic acid and an organic acid having a dissociation constant (pKa) value of from about 3.0 to about 5.0.

Applicants submit that the combined disclosures of the Gangadharan et al., Szentmiklósi et al., and Davidson et al. references, in any combination, fail to realize Applicants' invention of Claims 1-9 and 20-30. None of these applied references teaches a nasal composition comprising pyroglutamic acid in combination with an organic acid having a dissociation constant (pKa) value of from about 3.0 to about 5.0.

The Examiner contends that it would have been obvious to incorporate the pyroglutamic acid of Szentmiklósi et al. and the zinc gluconate of Davidson et al. into the moisturizer of Gangadharan et al., to thereby realize Applicants' invention. The Examiner then asserts that Applicants' claims directed to a nasal composition does not involve any unobvious difference between the structure of the claimed composition and those of the cited references, and that the manner or method in which such claimed compositions are to be utilized is not germane to the issue of patentability of the composition. Applicants respectfully disagree with the Examiner, and state that contrary to the Examiner's contentions the Examiner has applied references that the Examiner considers to be analogous to the art of nasal compositions. Moreover, Applicants' Claims 1-9 and 20-30 are directed to a nasal composition comprising pyroglutamic acid and a specifically defined organic acid, which nasal composition is not taught by either of the applied prior art references.

Applicants again submit that the combined disclosures of the Gangadharan et al., Szentmiklósi et al., and Davidson et al. references, in any combination, would not obviously lead the skilled artisan to a realization of Applicants' invention of Claims 1-9 and 20-30. The Examiner has admitted that the Szentmiklósi et al. reference fails to teach nasal formulations, and Applicants submit that Szentmiklósi et al. should provide some teaching or motivation for the skilled artisan to look to Szentmiklósi et al. for combining Szentmiklósi et al. with Gangadharan et al. Furthermore, there is no motivation to combine a reference such as Davidson et al., which is directed to delivering a zinc metal to the nasal membrane, with Gangadharan et al., which is directed to a moisturizer comprising a pyroglutamic acid salt and an organic acid. Applicants submit that there should be some teachings or suggestions in the references themselves in order to combine reference teachings. The particularly applied Gangadharan et al., Szentmiklósi et al., and Davidson et al. references provide no such teachings or suggestions for this applied reference combination.

Moreover, Applicants submit that Gangadharan et al. is completely silent to teaching or suggesting a nasal composition comprising pyroglutamic acid. Szentmiklósi et al. fail to teach or suggest nasal formulations. The Examiner contends that pyroglutamic acid salts and pyroglutamic acid are

functional equivalents. Applicants submit that pyroglutamic acid salts are not pyroglutamic acid regardless of the intended use, and that based on the teachings and suggestions of Gangadharan et al. and Szentmiklósi et al. there is no motivation for the skilled artisan to look to Szentmiklósi et al. for incorporating the pyroglutamic acid of Szentmiklósi et al. into a moisturizer of Gangadharan et al. Likewise, the skilled artisan would not be motivated to incorporate the zinc gluconate of Davidson et al. into the moisturizer of Gangadharan et al., to thereby realize Applicants' invention. The Examiner contends that it is obvious to take a component from various references for a realization of Applicants' invention of Claims 1-9 and 20-30. Specifically, the Examiner contends that the skilled artisan would combine the organic acid of Gangadharan et al. with the pyroglutamic acid of Szentmiklósi et al. and the zinc gluconate of Davidson et al. to result in a nasal composition as claimed by Applicants. Applicants disagree. Applied references should teach and suggest the nasal composition as claimed by Applicants or provide some motivation for reference combination, the particularly applied Gangadharan et al., Szentmiklósi et al., and Davidson et al. references fail to do just that.

In view of the foregoing remarks, it is submitted that the applied Gangadharan et al., Szentmiklósi et al., and Davidson et al. references, in any combination, would not obviously lead the skilled artisan to a realization of Applicants' invention of Claims 1-9 and 20-30, *prima facie* or otherwise. Accordingly the rejection of Claims 1-9 and 20-30 as being unpatentably obvious over Gangadharan et al. in view of Szentmiklósi et al. and Davidson et al. is improper, and should be withdrawn.

### Conclusions

Applicants have made an earnest effort to place the application in proper form and to distinguish their claimed invention from the applied prior art. WHEREFORE, reconsideration of this application, withdrawal of the rejection under 35 U.S.C. 103, and allowance of Claims 1-9 and 20-30 are respectfully requested.

Respectfully submitted,

Paul J. Rennie et al.

By: *Joan B. Cunningham*  
Joan B. Cunningham  
Agent for Applicants  
Registration No. 43,962  
(513) 622-3993

September 25, 2003  
Cincinnati, Ohio  
Customer No. 27752